
Attorney Docket No T2315-907789
UF#10831

**IN THE UNITED STATES PATENT & TRADEMARK OFFICE**
**BEFORE THE BOARD OF PATENT APPEALS & INTERFERENCES**

Appellant: Raymond J. Bergeron, Jr.

Serial No.: 10/091,591 Art Unit: 1614

Filed: March 7, 2002 Examiner: Anderson

For: Method and Composition for the Treatment of Diarrhea and Gastrointestinal Spasms

**BRIEF ON APPEAL**

Mail Stop: Appeal Brief Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The following Brief on Appeal is submitted in support of the appeal of the Office Action mailed February 27, 2008, wherein the Examiner finally rejected claims 1-6.

The application was filed with original claims 1-6. This is an appeal from the final rejection of claims 1-6.

A check in the amount of $255.00 for the appeal brief fee is enclosed. The Commissioner is hereby authorized to charge to Deposit Account No. 50-1165 (T2315-907789) any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this paper and to credit any overpayment to that Account. If any extension of time is required in connection

with the filing of this paper and has not been separately requested, such extension is hereby requested.

Respectfully submitted,

Date: July 14, 2008

Gianna J. Arnold
Reg. No. 36,358

Miles & Stockbridge, P.C.
1751 Pinnacle Drive
Suite 500
McLean, Virginia 22102-3833
(703) 610-8660

#4815-0018-3810

## TABLE OF CONTENTS

## TABLE OF AUTHORITIES

Statutes

## REAL PARTY IN INTEREST

The real party in interest herein is the University of Florida, to which the above-captioned application is assigned by virtue of an Assignment from the inventor executed 5/20/2002, which was recorded 6/3/2002, on Reel 012952 at Frame 0256.

## RELATED APPEALS AND INTERFERENCES

The invention described in the claims on appeal herein is related to none described in any other U.S. patent application on appeal to the U.S. Patent & Trademark Office Board of patent Appeals and Interferences known to appellant.

## STATUS OF CLAIMS

The above-captioned application was filed with original claims 1-6. This is an appeal from the final rejection of claims 1-6.

## STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final Office Action, mailed 2/27/2008.

## SUMMARY OF THE INVENTION

Of the claims on appeal, claim 1 is the only independent claim and is drawn to anti-diarrheal or anti-gastrointestinal anti-spasmodic pharmaceutical compositions comprising an effective amount of an active compound having the formula:

$R_1$ –$N^1(R_2)$-$(CH_2)_x$-$N^2H$-Q-$N^3H$-$(CH_2)y$-$N^4(R_3)$-$R_4$

wherein the variables have the meanings set forth at page 9, lines 1-10 of the specification and in claim 1.

## ISSUES ON APPEAL

Whether claims 1-6 comply with the written description requirement of 35 U.S.C. § 112, first paragraph.

Whether claims 1-6 comply with the written description requirement of 35 U.S.C. § 112, first paragraph as containing new matter.

Whether claims 1-6 are patentable under 35 U.S.C. § 103(a) over Frydman et al. (U.S. Patent No. 5,889,061).

## GROUPING OF CLAIMS

The appealed claims stand or fall together.

## ARGUMENTS

### The "written description" rejection under 35 U.S.C. 112, first paragraph

The limitation objected to by the Examiner is a "negative proviso" inserted in the claims by appellant to render the claims non-inclusive of certain species of compounds embraced by the original generic disclosure in the specification as well as the genus defined by the structural formula in the claims as originally filed.

It is a well settled rule of law that, before an applicant can insert a "negative proviso" in a claim, it must be clear that the inventor had "possession of the invention" within the meaning of 35 U.S.C. 112, first paragraph. See *In re Johnson,* 194 USPQ 187

(CCPA 1977).

The Examiner states in the final office action:

> *"---No support is seen in the specification for the proviso, "excluding the trans isomers of the compounds having the structures...." as recited in claim 1. The first excluded compound is CHX(3,4,3-trans), which is positively recited at pages 8 and 14 of the specification. This is the only specific compound identified in the specification. The second excluded compound is CHX(4,4,4-trans), which is neither positively nor negatively recited in the specification. Accordingly, Applicant has no written basis for the specific exclusion of CHX(4,4,4-trans) from the claims.---"*

Note that the Examiner does not deny that the genus defined by the structural formula in the specification and the original claims includes the compounds sought to be excluded by the "negative proviso". Nor could the Examiner attempt to do so, inasmuch as the original structural formula unequivocally includes the said compounds.

The Examiner's reasoning appears to be based on the erroneous premise that a disclosure must provide *in haec verba* support for the subject matter of a negative limitation in a claim. This is clearly contrary to the weight of the law regarding negative limitations which mandates only that it be clear to those skilled in the art from the disclosure that the inventor had possession of the subject matter sought to be disclaimed by the insertion of a negative limitation.

Thus, § 112, first paragraph, of the Patent Act states that the "specification shall contain a written description of the invention." The Court of Appeals for the Federal Circuit has held that "[t]o fulfill the written description requirement, the patent specification must describe an invention in sufficient detail that one skilled in the art can clearly conclude that the inventor invented what is claimed." *Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963, 967–968, 78 USPQ2d 1257, 1260 (Fed. Cir. 2006)

(quoting *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1364, 67 USPQ2d 1876, 1885 (Fed. Cir. 2003)). That same court has also cautioned that "[t]he disclosure as originally filed does not ... have to provide *in haec verba* support for the claimed subject matter at issue." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d at 1364, 67 USPQ2d at 1885 (internal citation omitted). "Although [the applicant] does not have to describe exactly the subject matter claimed, ... the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (citations omitted).

Put another way, "the applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991) (emphasis in original). The written description, although it need not include information that is already known and available to the experienced public, must be in sufficient detail to satisfy the statutory requirements, employing "[w]ords, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." *Space Systems/Loral, Inc. v. Lockheed Martin Corp.*, 405 F.3d 985, 987, 74 USPQ2d 1534, 1535 (Fed. Cir. 2005) (quoting *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997)). "Precisely how close the original description must come to comply with the description requirement of section 112 must be determined on a case-by-case basis." *Eiselstein v. Frank*, 52 F.3d 1035, 1039, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) (quoting *Vas-Cath*, 935 F.2d at 1561, 19 USPQ2d at 1116).

With respect to negative limitations, the CAFC has determined that an "express intent to confer on the claim language the novel meaning imparted by [the] negative limitation" is required, such as an "express disclaimer or independent lexicography in the written description." *Omega Engineering, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1323, 67 USPQ2d 1321, 1327 (Fed. Cir. 2003) (internal citations omitted).

The decision in In re Johnson, 194 USPQ 187 (CCPA 1977) is based on facts almost identical to those here. The court noted in In re Johnson, "[t]he notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of §112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute." 194 USPQ at 196 (emphasis added). Clearly, Johnson holds that the disclosure of a genus is sufficient to support a claim to the genus minus included species.

It is respectfully submitted therefore that applicant's disclosure clearly shows that the inventor had possession of the genus defined in the original claim as well as the species embraced thereby. Accordingly, the negative limitation objected to by the Examiner is appropriate. A reversal of this ground of rejection is, therefore, respectfully requested.

**The "new matter rejection" under 35 U.S.C. 112, first paragraph**

The Examiner states in the final Office Action:

> "*---In the amendment to the claims filed 11/26/2007, claim 1 was amended to recite the limitation wherein "Q is a cycloalkyl group having from 5 to 10 carbon atoms". Previously presented claim 1 had the limitation wherein Q is a cycloalkyl group having from 3 to 10 carbon atoms. No*

*support is found in the originally filed disclosure for cycloalkyl groups having from 5 to 10 carbon atoms as recited in the instant claims. The only specific compound disclosed contains a cyclohexyl group (i.e., 6 carbon atoms). There are no compounds recited in the original disclosure that would provide support for the limitation of Q being a cycloalkyl group having from 5 to 10 carbon atoms---".*

Although the Examiner refers to this ground of rejection as a "new matter" rejection, it would appear to be identical in nature to the "written description" rejection discussed above. Thus, appellant amended the claims to exclude cycloalkyl groups containing 3 and 4 carbon atoms, whereas the genus defined in the specification and the original claims included such cycloalkyl groups. Accordingly, the limitation objected to by the Examiner is a "negative proviso", very similar to that discussed above.

It would also appear obvious that if the negative proviso discussed above is appropriate since the excluded compounds were embraced by the generic disclosure, then the present limitation that effectively excludes compounds embraced by the same generic disclosure is also appropriate for the reasons set forth above. Accordingly, a reversal of this ground of rejection is respectfully requested.

**The Rejection under 35 U.S.C. 103**

The rejection of the claims over the cited prior art requires that the limitation in the body (as opposed to the preamble) of the claims that the composition contain "an amount effective" to produce an "anti-diarrheal or gastrointestinal anti-spasmodic" action be ignored. The Examiner states:

"*---It is well established that intended use does not impart patentability in a composition claim. See In re Zierden, 411 F.2d 1325, 1329, 162 USPQ 102, 104 (CCPA 1969): A mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable. As we said in In re Lemin, 51 CCPA 942,326 F.2d 437,140 USPQ 273,276 (1964),*

> *Appellants are clearly correct in demanding that the subject matter as a whole must be considered under 35 U.S.C. 103. But in applying the statutory test, the differences over the prior art must be more substantial than a statement of the intended use of an old composition. ... It seems to us that the composition ... would be exactly the same whether the user were told to cure pneumonia in animals with it ... or to promote plant growth with it (as here). The directions on the label will not change the composition....*
>
> *See also, In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("[t]the discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, cannot impart patentability to claims to the known composition"). Accordingly, the claims simply require a composition comprising a compound of formula I and a pharmaceutically acceptable carrier. As such, the compositions of Frydman et al. render prima facie obvious the instantly claimed compositions.---"*

The Examiner has acknowledged that the prior art is silent as to "effective amounts" of anything disclosed therein to produce an "anti-diarrheal or gastrointestinal anti-spasmodic" action.

The Examiner is apparently unaware of the several decisions of the CAFC which hold that such "effective amount" limitations in the body of the claim are substantive limitations which cannot be ignored when determining patentability.

Attention is directed to the decision in *Abbott Laboratories v. Baxter Pharmaceuticals*, 80 U.S.P.Q.2d. 1641 (Fed. Cir. 2006). Abbott owned U.S. Patent No. 5,990,176 (the '176 patent), which claimed compositions and methods of preventing the degradation of sevoflurane anesthetic by adding an effective amount of certain specific Lewis acid inhibitors:

> "---Claim 1.
> An anesthetic composition comprising:
> a quantity of sevoflurane; and a Lewis acid inhibitor in an amount effective to prevent degradation by a Lewis acid of said quantity of sevoflurane, said Lewis acid inhibitor selected from the group consisting of water, butylated hydroxytoluene, methylparaben, propylparaben, propofol, and thymol.

Claim 6.
A method of preventing degradation by a Lewis acid of a quantity of sevoflurane, the method comprising the steps of: providing a quantity of sevoflurane; providing a Lewis acid inhibitor in an amount sufficient to prevent degradation by a Lewis acid of said quantity of sevoflurane, said Lewis acid inhibitor selected from the group consisting of water, butylated hydroxytoluene, methylparaben, propylparaben, propolol, and thymol; combining said quantity of sevoflurane and the Lewis acid inhibitor in an amount sufficient to prevent the degradation by a Lewis acid of said quantity of sevoflurane.

Claim 10.
A method of preventing degradation by a Lewis acid of a quantity of sevoflurane, the method comprising the steps of: providing a quantity of sevoflurane; providing water in an amount sufficient to prevent degradation by a Lewis acid of said quantity of sevoflurane; combining said quantity of sevoflurane and said water in an amount sufficient to prevent the degradation by a Lewis acid of said quantity of sevoflurane.---"

During prosecution of the '176 patent application, Abbott filed an Information Disclosure Statement (IDS) with the United States Patent and Trademark Office (USPTO). The IDS listed a reference indicating that at least one year before the filing date of the '176 patent, Abbott sold sevoflurane in glass bottles with a water content up to 131 ppm. Baxter seized upon this disclosure as a limit on the scope of the claims. Therefore, Baxter asserted that its generic sevoflurane with a water content of no more than 130 ppm falls within the prior art and does not infringe the '176 patent.

The district court agreed.

The CAFC reversed, stating:

"- - -The primary issue on appeal is the district court's construction of the claim term "effective amount." **At the outset, this court notes that the term "effective amount" has a customary usage.** Under this usage, the term would mean "the amount of Lewis acid inhibitor that will prevent the degradation of sevoflurane by a Lewis acid." See Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1299, 1304 - - - Because the patentee did not deviate from the accustomed meaning of the disputed

> claim term, the term "effective amount" is construed in view of its ordinary and customary meaning. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) (stating that claim terms are afforded a "heavy presumption" that their ordinary and customary meanings apply). At a minimum, the '176 patent provides support for defining an "effective amount" of inhibitor to be the amount of Lewis acid inhibitor needed to stabilize sevoflurane housed in a particular glass vessel under a given set of environmental conditions. - - - Particularly because the prior sale involved sevoflurane in a specific glass container with a water content of no more than 131 ppm, Abbott's disclosure to the USPTO did not disavow or relinquish all water concentrations below 131 ppm in other conditions. In the context of this invention, Abbott's disclosure did not expressly disavow claim scope. See York Prods., Inc. v. Cent. Tractor Farm & Family Ctr., 99 F.3d 1568, 1575-76 (Fed. Cir. 1996) (emphasis added)---"

Clearly, *Abbott* stands for the proposition that the recitation of an effective amount in the body of a claim to accomplish a specific purpose is a substantive limitation which may simply be ignored in determining the patentability of claims in which it appears.

See also Amgen Inc. v. Hoechst Marion Roussel, Inc. (*Amgen V*), 469 F.3d 1039 (Fed. Cir. 2006), *denying reh'g and reh'g en banc of* 457 F.3d 1293 (Fed. Cir. 2006), *petition for cert. filed*, 2007 WL 906697 (U.S. Mar. 22, 2007) (No. 06-1291). The CAFC specifically held that the district court had erred in failing to construe explicitly the term "therapeutically effective amount," which the panel deemed necessary to determine whether the '422 Patent was anticipated by a prior art clinical study.

Inasmuch, therefore, as the Examiner has admittedly ignored the limitation in the claims as to "effective amounts" and has admitted that the prior art relied upon does not disclose these effective amounts, a reversal of this ground of rejection is clearly mandated.

*(Remainder of Page Left Blank Intentionally)*

## CONCLUSION

It is respectfully requested that the final rejection of record be reversed and the application remanded to the Examiner for immediate allowance.

Respectfully submitted,

Date: July 14, 2008

Gianna J. Arnold
Reg. No. 36,358

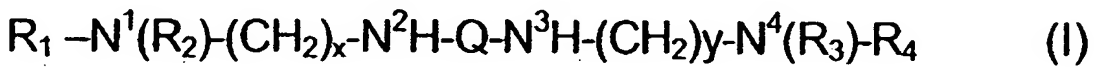
Miles & Stockbridge, P.C.
1751 Pinnacle Drive
Suite 500
McLean, Virginia 22102-3833
(703) 610-8660

#4815-0018-3810

## APPENDIX OF CLAIMS ON APPEAL – SERIAL NO. 10/091,591

**Claims 1-6**

1. An anti-diarrheal or gastrointestinal anti-spasmodic pharmaceutical composition comprising [A] an effective amount of a compound having the formula:

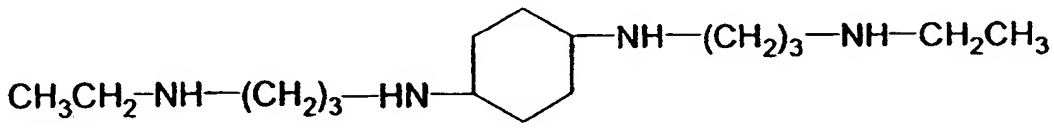


$$R_1 - N^1(R_2)-(CH_2)_x-N^2H-Q-N^3H-(CH_2)y-N^4(R_3)-R_4 \qquad (I)$$

wherein: R1, R2, R3 and R4 are the same or different and are H, alkyl, cycloalkyl or aralkyl having from 1 to 12 carbon atoms, or a heterocyclic group having from 3 to 10 atoms wherein the hetero atom is said N1 or N4; Q is a cycloalkyl group having from 3 5 to 10 carbon atoms;

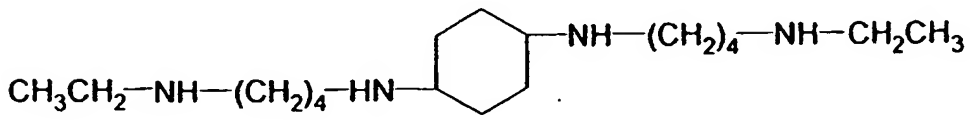
x is an integer from 3 to 6, inclusive;

excluding the trans isomers of the compounds having the structures:





and



and y is an integer from 3 to 6, inclusive; or (II) a salt thereof with a pharmaceutically acceptable acid; and [B] a pharmaceutically acceptable carrier therefor.

2. The composition according to claim I wherein Q is connected either cis or trans as the (1,2), (1,3), (1,4), (1,5) or (1,6) isomer.

3. The composition according to claim I wherein Q is cyclohexyl.

4. The composition according to claim I wherein x is 3 and y is 3.

5. The composition according to claim 1 wherein x is 3, y is 3, R1 and R3 are both H and R2 and R4 are both ethyl.

6. The composition according to claim 1 wherein Q is cyclohexyl; x and y are 3; R1 and R3 are both H, and R2 and R4 are both ethyl.

## EVIDENCE APPENDIX

Appellant submits no additional evidence herewith.

## RELATED PROCEEDINGS APPENDIX

None.